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| Sam Pasternack | | | BAKER, MAURIE GARCIA | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. **09/803,319**

Applicant(s)

Anderson et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit 1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on Aug 20, 2003 2b) X This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-58 4a) Of the above, claim(s) 7, 12, 13, 21-56, and 58 ______ is/are withdrawn from consideration. is/are allowed. 5) (Claim(s) 6) 💢 Claim(s) <u>1-6, 8-11, 14-20, and 57</u> is/are rejected. 7) Claim(s) is/are objected to. are subject to restriction and/or election requirement. 8) Claims Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) X Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s).

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

6) Other:

5) Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.
- 2. The Response filed August 20, 2003 (Paper No. 21) is acknowledged. Claims 1, 2 and 12 were amended, claims 55-58 were added and no claims were cancelled. Therefore, claims 1-58 are pending.
- 3. Applicant's election of species carries over to the prosecution in this continued examination case. Claim 12 has been amended to omit "drugs" from the Markush group. Thus this claim no longer reads on the elected species. Newly added claims 55, 56 and 58 also do not read on the elected species. Thus claims 12, 55, 56 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.
- 4. Also, claims 7 and 13 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking

claim. Furthermore, claims 21-54 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made without traverse in Paper No. 13.

5. Therefore, claims 1-6, 8-11, 14-20 and newly added claim 57 are under examination in this action.

Status of Rejections

6. The previous rejections under 35 U.S.C. 112, first and second paragraphs and under 35 U.S.C. 102(b) over Khrapko et al are withdrawn in view of applicant's claim amendments and arguments. New rejections have been made in this action as necessitated by applicant's amendments.

New Rejections Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-6, 8-11, 14-20 and newly added claim 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saltzman et al (J. Biomed. Mat. Res. 1991) in view of Kapur et al (US 6,548,263) and Schultz et al (US 5,985,356).

Saltzman et al teaches the growth and behavior of cells on synthetic polymer surfaces (see Abstract). The reference clearly teaches a variety of synthetic polymers, see Table 1 and associated text. These read on instant claims 10 and 11. The polymers of Saltzman are prepared on glass coverslips, reading on the claimed "base" of instant claims 3 and 4. As this reads directly on the "base" claimed, the surface is assumed to inherently have the claimed "cytophobic" properties. The polymers are thin films (non-monolayers) that are prepared from a solution of the polymer (see page 743), reading on claims 2, 8, 9 and the newly added limitation to "soluble synthetic polymer". The polymers are dried after preparation and stored desiccated (page 743), reading on the limitation to "dry polymeric biomaterial elements".

Saltzman et al lacks the specific teaching of making a microarray of their polymer samples, the use of a hydrogel as a cytophobic surface (i.e. instant claims 4-6) and the inclusion of additional compounds (i.e. instant claim 57).

However, it was well known in the art at the time of filing to use an array format for ease in testing of a large number of samples. For example, Kapur et al teaches making a substrate for selective cell patterning allowing for cell placement in controlled locations (see e.g. Abstract and Figure 1). Kapur et al teaches arrays of various sizes (see, e.g., Examples 2-3 and column 39), reading on instant claims 15-20. The reference specifically teaches that arrays of multiple cell types on a common substrate are needed and advantageous (see, e.g., column 3, lines 38-44). Kapur et al also teaches using a hydrogel as a cytophobic surface, see Example 4, specifically column 42, lines 4-19. The reference also teaches that various cell binding, marker and other molecules can be used in the arrays, including "drugs", see, e.g., column 18, line 60 – column 19, line 65, especially column 19, line 48.

Moreover, Schulz et al demonstrates that making arrays of synthetic polymers was known in the art as well. The reference specifically teaches making arrays of materials such as non-biological (i.e. synthetic) organic polymers on a single substrate surface for testing; see column 1, lines 11-26 and Example B in columns 33-34. Note that Schulz et al specifically makes an array of synthetic styrene polymers in Example B. The reference also teaches a variety of array sizes, see, e.g. column 4, lines 30-47. This reads on instant claims 15-20.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to prepare the synthetic polymer surfaces of Saltzman et al in an array format as demonstrated by Kapur et al and Schulz et al. Kapur et al demonstrates that it was well known in the art to make an array substrate for selective cell patterning, and to further use hydrogels and additional molecules therein. Schultz et al demonstrates specifically making arrays of synthetic polymers. One of ordinary skill would have been motivated to prepare the synthetic polymer surfaces of Saltzman et al in an array format in order to more easily screen the surfaces and to allow for "high throughput and high biological content screening of cells" (see Kapur et al, column 3, lines 43-44).

Status of Claims/Conclusion

- 10. No claims are allowed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.
- 12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to

the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D. November 14, 2003

> MAURIE GARCIA BAKER PH.D PRIMARY EXAMINER